

that, after pressing button 208 to begin the flow of anesthetic, “the anesthetic flows slowly [at first] in order to overcome the breakaway force of the piston 16. After 1 to 2 seconds, the microprocessor 200 instructs the motor 202 to drive mechanism 204 at a speed which corresponds to the desired injection pressure.” *See*, Hodosh, column 10, lines 20-24.

Hodosh’s initial slow flow of anesthetic is simply a “bleed-off” that occurs when an incompressible fluid, such as an anesthetic, is compressed in a container provided with one outlet, which in this case is the annular stem portion 44 that conducts anesthetic to the needle. The interval taken to overcome the breakaway force of the piston is brief, after which the microprocessor commands an injection speed that will produce the desired, single injection pressure. Applicants submit that this will, at best, form an initial trickle of anesthetic which is followed by a step change to the single desired injection pressure. The initial “bleed-off” is just that, it is not an injection speed or pressure, it is a priming step. Hodosh acknowledges this by disclosing that after “bleed-off” the motor is increased to a speed that “corresponds to the desired injection pressure.” Column 10, lines 20-24.

Further, even if the Examiner maintains his contention regarding the bleed-off, Hodosh does not increase the pressure “gradually” as claimed. Hodosh starts at the bleed-off pressure and then converts directly to the injection pressure with no intermediate pressures to gradually go from the bleed-off pressure to the injection pressure. *See*, Hodosh, column 10, lines 16-28.

Regarding claim 15 and claim 2, the Examiner contends that Hodosh makes a buzzing sound¹ and Applicants respectfully traverse the Examiner's statement of inherency. Applicants have thoroughly reviewed Hodosh and the reference is silent regarding any sound produced by the device. The Examiner's only statement in support of the inherency is that "any motorized device will output sound."² However, according to MPEP § 2112 (IV):

The fact that a certain result or characteristic may occur or be present in the prior art **is not sufficient to establish the inherency** of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)[emphasis added] ... "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted)[emphasis added] ... "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

Applicants submit that just the fact that Hodosh discloses a motor is not sufficient to establish the inherency that the device outputs sound to the user. Multiple ways are known to those of ordinary skill in the art to suppress the output of sound. The housing may be insulated to prevent the output of noise from the motor. Further, a motor can be designed to minimize sound and vibration outputs which can be used alone, or in combination with the insulation.

Applicants also submit that the reduction of sounds and vibrations would be a very important concern for a device used in a patient's mouth. Naturally, the device is located proximate the patient's ears and any constant buzzing would be annoying. Further, since the device is

¹ Office Action dated September 21, 2006, page 3.

² Office Action dated March 28, 2006, page 3.

designed to enter the patient's gums, it can transmit sound and vibration to the jaw bone, which is transmitted to the ear and is also uncomfortable to the patient.

Thus, Applicants submit that just because a motor may make a sound, does not establish that it is inherent that Hodosh's device outputs a sound as claimed.

Regarding claims 12, 13, 16, and 17, Applicants submit that the Hodosh is not capable of, as the Examiner states, "holding cartridges smaller than the ones depicted in the drawings."³ Again, the Examiner has set forth a statement of inherency and the rules regarding the use of an inherent disclosure are set forth above. Applicants respectfully traverse the Examiner's statement of inherency.

Applicants have thoroughly reviewed Hodosh and the reference is silent regarding smaller cartridges. Hodosh, however, is explicit in depicting a single size. Further, Applicants submit that Hodosh would not function with a smaller cartridge. It is clear from at least Figures 1, 3, and 7, that receiving member 28 is designed to cover both the front and the rear of the cartridge 12 once it is inserted through slot 32. One of ordinary skill in the art would be aware that this is for safety and utility reasons. A properly sized slot 32 assures a close fit for the cartridge 12, reducing the chance that the cartridge will fall out prior to setting the end 80 of the rack member 58. Further, the end of the cartridge 12 is covered in the embodiment disclosed in Hodosh and one of ordinary skill in the art is aware that this covering can protect the user if there is any spray or leakage when piston 16 is initially engaged by the end of the rack or any time during the injection process.

Switching to a smaller cartridge results in a very loose fit for the cartridge inside receiving member 28 prior to being engaged by the end 80. This loose fit greatly increases the chance that the

cartridge will fall out. Additionally, the piston end of the cartridge is exposed and the user can be likewise exposed to spray or leakage. Furthermore, changing the size of slot 32 to alleviate the above shortcomings is not taught or suggested by Hodosh, nor would allow Hodosh to function properly. Changing the size of the slot will increase the difficulty of inserting and removing the cartridges of the disclosed size.

Given the above, it is not inherent that Hodosh could use cartridges of a smaller size. Also, one of ordinary skill in the art looking to solve the problem of having less medication per cartridge would first look to underfilling the full size cartridge disclosed in Hodosh.

Thus, independent claims 1 and 15 are patentable over Hodosh. Further, 2, 11-13 and 16-17 depend from the independent claims and are allowable based at least on the arguments above. Applicants respectfully request that the rejection be withdrawn.

³ Office Action dated September 21, 2006, page 4.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

The Examiner is respectfully requested to contact the undersigned at the telephone number indicated below if the Examiner believes any issue can be resolved through either a Supplemental Response or an Examiner's Amendment.

Dated: December 27, 2006

Respectfully submitted,

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